RISK MITIGATION AND RESOURCE SAVINGS FOR BIOLOGICAL DRUG PRODUCT WITH COMPUTATIONAL FLUID DYNAMICS SIMULATION

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Computational Fluid Dynamics (CFD) Simulation is used to predict uniformity of biological formulations and impact from mixing equipment changes. Such changes occur during process transfer from one site to the other or upon batch size alterations. Experimental runs are traditionally required during such switch, which could be expensive and resource-intensive, especially if it occurs in a commercial manufacture environment. The current study is aimed to reduce the number of experimental runs at scale by using CFD. Steady state CFD mixing models are developed at smaller scales using physical properties of surrogate fluids. Experimental runs are designed and conducted to verify the validity of assumption made in the CFD models, such as the negligibility of starting period. The results show that assumptions made in the CFD models are valid and the CFD models yield outcomes similar to that of experiment, i.e., a tracer is uniformly distributed at similar time frame between the CFD simulations and the corresponding experiments. Large scale mixing models are further developed and used to support an equipment change as well as a batch size increase in the same mixer while mixing parameters are requested to be maintained. The CFD simulation suggest there is negligible impact in both cases and mixing process parameters can be maintained. Validation of the CFD models at the large scale with experiment is planned.